

Attorney Docket No.: KUZ-0021
Inventors: Suzuki et al.
Serial No.: 10/517,468
Filing Date: December 6, 2004
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In the Specification:

Please replace the paragraph beginning at line 20 of page 6 with the following:

Namely, the invention relates to a patch comprising a substrate made of a polyester-based film and a drug-containing adhesive layer laminated thereon, wherein the surface roughness (Ra) of the polyester-based film surface on the side in contact with the adhesive layer is from 0.05 to 0.8 ~~µm~~Ra µm.

Please replace the paragraph beginning at line 7 of page 10 with the following:

The patch of the invention is characterized in that the polyester-based film being a substrate has a surface roughness. By roughening said film surface, anchoring properties between the substrate and an adhesive layer is improved, making it possible to afford a patch excellent in use feeling, which gives no so-called adhesive residue when the patch is applied to the skin and then peeled off. Therefore, if such an effect is obtained, any method may be used as a method to roughen the surface, though, for example, sandblasting treatment can preferably be used. Moreover, in order to improve anchoring properties, the treatment is done so that the surface roughness (Ra) becomes

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0.05-0.8 ~~µm~~Ra µm, preferably 0.3-0.7 ~~µm~~Ra µm. That is why an anchoring collapse easily occurs as the surface roughness becomes small, whereby even the substrate and the adhesive layer are laminated, they do not adhere favorably, giving a tendency that an enough anchoring power is not obtained, and on the other hand, anchoring properties is improved as the surface roughness becomes large, though pinholes tend to be made in the substrate easily.

Please replace the paragraph beginning at line 21 of page 22 with the following:

In the composition, the components except sodium acetate and fentanyl citrate were dissolved and mixed at 180°C, then added with the remaining components, followed by dispersion till the mixture became uniform, and then the mixture was spread on PET film of 25 µm so that the adhesive layer became 50 µm to obtain the patch of the invention by the conventional method. Further, the PET film was sandblasted on the one side in advance in such a manner that the surface roughness (Ra) became 0.1 ~~µm~~Ra µm.

Please replace the paragraph beginning at line 4 of page 23 with the following:

In the same composition as that of the example 1-1, the mixture was spread on PET film of 10 µm so that the adhesive

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layer became 50 μm to obtain the patch of the invention by the conventional method. Further, the PET film was sandblasted on the one side in advance in such a manner that the surface roughness (Ra) became 0.1 ~~μmRa~~ μm .

Please replace the paragraph beginning at line 11 of page 23 with the following:

In the same composition as that of the example 1-1, the mixture was spread on PET film of 3.5 μm so that the adhesive layer became 50 μm to obtain the patch of the invention by the conventional method. Further, the PET film was sandblasted on the one side in advance in such a manner that the surface roughness (Ra) became 0.1 ~~μmRa~~ μm .

Please replace the paragraph beginning at line 18 of page 23 with the following:

In the same composition as that of the example 1-1, the mixture was spread on PET film of 25 μm so that the adhesive layer became 50 μm to obtain the patch of the invention by the conventional method. Further, the PET film was sandblasted on the one side in advance in such a manner that the surface roughness (Ra) became 0.3 ~~μmRa~~ μm .

Please replace the paragraph beginning at line 25 of page 23 with the following:

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In the same composition as that of the example 1-1, the mixture was spread on PET film of 10 μm so that the adhesive layer became 50 μm to obtain the patch of the invention by the conventional method. Further, the PET film was sandblasted on the one side in advance in such a manner that the surface roughness (Ra) became 0.3 ~~μmRa~~ μm .

Please replace the paragraph beginning at line 6 of page 24 with the following:

In the same composition as that of the example 1-1, the mixture was spread using PET film of 40 μm so that the adhesive layer became 50 μm to obtain the patch of the invention by the conventional method. Further, the PET film was sandblasted on the one side in advance in such a manner that the surface roughness (Ra) became 0.3 ~~μmRa~~ μm .

Please replace the paragraph beginning at line 13 of page 24 with the following:

In the same composition as that of the example 1-1, the mixture was spread using PET film of 25 μm so that the adhesive layer became 50 μm to obtain the patch of the invention by the conventional method. Further, the PET film was sandblasted on the one side in advance in such a manner that the surface roughness (Ra) became 0.6 ~~μmRa~~ μm .

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Please replace the paragraph beginning at line 20 of page 24 with the following:

In the same composition as that of the example 1-1, the mixture was spread on PET film of 10 μm so that the adhesive layer became 50 μm to obtain the patch of the invention by the conventional method. Further, the PET film was sandblasted on the one side in advance in such a manner that the surface roughness (Ra) became 0.6 ~~μmRa~~ μm .

Please replace the paragraph beginning at line 1 of page 25 with the following:

In the same composition as that of the example 1-1, the mixture was spread using PET film of 50 μm so that the adhesive layer became 50 μm to obtain the patch of the invention by the conventional method. Further, the PET film was sandblasted on the one side in advance in such a manner that the surface roughness (Ra) became 0.6 ~~μmRa~~ μm .

Please replace the paragraph beginning at line 8 of page 25 with the following:

In the same composition as that of the example 1-1, the mixture was spread using PET film of 25 μm so that the adhesive layer became 50 μm to obtain a patch by the conventional method. Further, the PET film was sandblasted

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on the one side in advance in such a manner that the surface roughness (Ra) became 0.01 ~~µm~~Ra µm.

Please replace the paragraph beginning at line 14 of page 25 with the following:

In the same composition as that of the example 1-1, the mixture was spread using PET film of 10 µm so that the adhesive layer became 50 µm to obtain a patch by the conventional method. Further, the PET film was sandblasted on the one side in advance in such a manner that the surface roughness (Ra) became 0.01 ~~µm~~Ra µm.

Please replace the paragraph beginning at line 20 of page 25 with the following:

In the same composition as that of the example 1-1, the mixture was spread using PET film of 25 µm so that the adhesive layer became 50 µm to obtain a patch by the conventional method. Further, the PET film was sandblasted on the one side in advance in such a manner that the surface roughness (Ra) became 1.0 ~~µm~~Ra µm.

Please replace the paragraph beginning at line 26 of page 25 with the following:

In the same composition as that of the example 1-1, the mixture was spread using PET film of 10 µm so that the

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adhesive layer became 50 μm to obtain a patch by the conventional method. Further, the PET film was sandblasted on the one side in advance in such a manner that the surface roughness (Ra) became 1.0 ~~μmRa~~ μm .

Please replace the paragraph beginning at line 6 of page 26 with the following:

In the same composition as that of the example 1-1, the mixture was spread using PET film of 25 μm so that the adhesive layer became 50 μm to obtain a patch by the conventional method. Further, the PET film was sandblasted on the one side in advance in such a manner that the surface roughness (Ra) became 1.3 ~~μmRa~~ μm .

Please replace the paragraph beginning at line 12 of page 26 with the following:

In the same composition as that of the example 1-1, the mixture was spread using PET film of 10 μm so that the adhesive layer became 50 μm to obtain a patch by the conventional method. Further, the PET film was sandblasted on the one side in advance in such a manner that the surface roughness (Ra) became 1.3 ~~μmRa~~ μm .

Please replace Table 1 beginning at line 2 of page 27 with the following:

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Table 1

Surface Roughness <u>Ra</u> (<u>μmRa</u> <u>μm</u>)		Anchoring Properties
Example 1-1	0.1	O
Example 2-1	0.3	O
Example 3-1	0.6	O
Comparative example 1-1	0.01	X
Comparative example 2-1	1.0	O
Comparative example 3-1	1.3	O

(PET 25 μm)

Please replace Table 2 beginning at line 28 of page 27 with the following:

Table 2

Surface roughness <u>Ra</u> (<u>μmRa</u> <u>μm</u>)		Thickness of films (<u>μmRa</u> <u>μm</u>)	Substrate pinhole
Example 1-1	0.1	25	O
Example 1-2		10	O
Example 1-3		3.5	O
Example 2-1	0.3	25	O
Example 2-2		10	O
Example 2-3		40	O
Example 3-1	0.6	25	O
Example 3-2		10	O
Example 3-3		50	O
Comparative example 1-1	0.01	25	O
Comparative example 1-2		10	O
Comparative example 2-1	1.0	25	X
Comparative example 2-2		10	X
Comparative example 3-1	1.3	25	X
Comparative example 3-2		10	X

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Please replace the paragraph beginning at line 5 of page 29 with the following:

As is evident from Table 1, in the adhesive tapes with the surface roughness of the examples 1-3 no so-called adhesive residue was observed when applied to the skin and then peeled off, showing favorable anchoring properties. On the contrary, when the surface roughness is too small, the anchoring property becomes unfavorable, and as is evident from Table 2, when the surface roughness is too large, the anchoring property is favorable, though pinholes are generate in the substrate. Therefore, in order to get preferable anchoring property and in order not to generate pinholes in the substrate, the surface roughness (Ra) is preferably 0.05-0.8 ~~um~~Ra um which is the condition that is consistent with both. Compared with the comparative examples 1-3, the examples 1-3 generate no pinhole in the substrates, giving the excellent patches with favorable anchoring properties.